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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/065,800	11/20/2002	Shihshieh Huang	38-21(52573)	6564
27161	7590	09/26/2005	EXAMINER	
MONSANTO COMPANY			FOX, DAVID T	
800 N. LINDBERGH BLVD.			ART UNIT	
ATTENTION: G.P. WUELLNER, IP PARALEGAL, (E2NA)			PAPER NUMBER	
ST. LOUIS, MO 63167			1638	

DATE MAILED: 09/26/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/065,800

Applicant(s)

HUANG, SHIHSHIEH

Examiner

David T. Fox

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 June 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-35 is/are pending in the application.
- 4a) Of the above claim(s) 12-19, 26 and 30-34 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11, 20-25, 27-29 and 35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 November 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 19 February 2003.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

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Applicant's election with traverse of Group I in the reply filed on 27 June 2005 is acknowledged. The traversal is on the ground(s) that Groups I-IV are all related as being means of restoring male fertility, and that Groups V and VI are related by requiring the plants or genes of Groups I-IV. This is not found persuasive because each of Groups I-IV involve different means, such as topical application of cytokinin, a hormone different from gibberellin, or plant transformation with genes encoding different types of products, including antisense RNA, ribozymes, and dominant negative mutant proteins. Furthermore, Applicant has admitted that Groups V and VI involve additional breeding steps and breeding partners, as they have proposed an alternative grouping which still separates Groups V and VI from the others (see page 4 of the Election of 27 June 2005, bottom paragraph).

The requirement is still deemed proper and is therefore made FINAL.

The application should be reviewed for errors. Errors appear, for example, on page 7 of the specification, paragraph [0027], where "Gordonet al" should be replaced with ---Gordon-Kamm et al---; on page 18, paragraph [0067], where "stage 3" should be replaced with ---stage -3---; and on page 19, line 1, where "stage 2" should be replaced with ---stage -2---. See the provisional application, page 7, line 9; page 18, line 10; and page 18, line 12, respectively. All amendments to the specification should comply with 37 CFR 1.121(b).

Claims 21-23 and 29 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should depend on other

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claims in the alternative only. Amendment of the claims to insert ---one--- after "any" would obviate this objection. See MPEP § 608.01(n).

Claims 23-25 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend upon another multiple dependent claim. See MPEP § 608.01(n).

In the interest of compact prosecution, the claims have been treated on the merits. Such treatment does not relieve Applicant of the responsibility to respond to these objections.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-11, 20-25, 27-29 and 35 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are broadly drawn to methods of transforming plants with a *gai* gene from any source plant species, and of any sequence. In contrast, the specification only provides guidance for the use of the *gai* gene from *Arabidopsis* for plant transformation.

The Federal Circuit has recently clarified the application of the written description requirement. The court stated that a written description of an invention "requires a precise definition, such as by structure, formula, [or] chemical name, of the claimed subject matter sufficient to distinguish it from other materials." *University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1568; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). The court also concluded that "naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material." *Id.* Further, the court held that to adequately describe a claimed genus, Patent Owner must describe a representative number of the species of the claimed genus, and that one of skill in the art should be able to "visualize or recognize the identity of the members of the genus." *Id.*

See MPEP Section 2163, page 156 of Chapter 2100 of the August 2001 version, column 2, bottom paragraph, where it is taught that

[T]he claimed invention as a whole may not be adequately described where an invention is described solely in terms of a method of its making coupled with its function and there is no described or art-recognized correlation or relationship between the structure of the invention and its function. A biomolecule sequence described only by a functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence.

Given the claim breadth and lack of guidance as discussed above, the specification fails to provide an adequate written description of the genus of sequences as broadly claimed. Given the lack of written description of the claimed genus of sequences, any method of using them, such as transforming plant cells and plants therewith, and the resultant products including the claimed

transformed plant cells and plants containing the genus of sequences, would also be inadequately described. Accordingly, one skilled in the art would not have recognized Applicant to have been in possession of the claimed invention at the time of filing. See the Written Description Requirement guidelines published in Federal Register/ Vol. 66, No. 4/ Friday January 5, 2001/ Notices: pp. 1099-1111.

See also *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ 2d 1016 at 1021, (Fed. Cir. 1991) where it is taught that a gene is not reduced to practice until the inventor can define it by "its physical or chemical properties" (e.g. a DNA sequence).

See also *University of California v. Eli Lilly and Co.*, 43 USPQ2d 1398 (Fed. Cir. 1997), which teaches that the disclosure of a process for obtaining cDNA from a particular organism and the description of the encoded protein fail to provide an adequate written description of the actual cDNA from that organism which would encode the protein from that organism, despite the disclosure of a cDNA encoding that protein from another organism.

Claims 1-11, 20-25, 27-29 and 35 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 1-11, 20-25, 27-29 and 35 are broadly drawn to methods of plant transformation with any *gai* gene from any plant source of any sequence, for the production of reversibly male-sterile plants. Claims 1-3, 5-11, 20-25, 27-29 and

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35 are broadly drawn to the use of any type of promoter causing expression constitutively, inducibly, or in a wide variety of tissues, operably linked to a *gai* coding sequence for the production of reversibly male sterile plants. Claims 5-6 and 10-11 are drawn to applications of any type of cytokinin for the reversal of male sterility in plants transformed with a *gai* gene. Claims 5-9 and 11 are drawn to cytokinin application at any developmental stage, for the reversal of male sterility in plants transformed with a *gai* gene.

In contrast, the specification only provides guidance for plant transformation with the *Arabidopsis gai* gene for the production of male sterile plants, wherein said male sterility is reversible when kinetin is applied to plants prior to the development of male tissues, and when the *gai* coding sequence is operably linked to an anther-specific promoter.

Plant transformation for induction of reversible male sterility is unpredictable. Huang et al (2003) teach that kinetin treatment of plants containing the *Arabidopsis gai* gene caused conversion of sterile stamens to petals rather than fertile stamens (see, e.g., page 1278, column 2, middle paragraph). Huang et al also teach that some gibberellic acid mutants confer the opposite effect on plants containing them, namely male fertility (see, e.g., page 1278, column 1, first full paragraph). Furthermore, Huang et al teach that stamen-specific rather than pollen-specific promoters are required to effect complete male sterility (see, e.g., page 1271, column 2, top paragraph; page 1277, paragraph bridging the columns).

The application of cytokinins to transformed plants to restore fertility is unpredictable. Singh et al (1992, Plant Science) teach that application of the cytokinin cis-zeatin actually *induced* male sterility (see, e.g., page 153, column 1, penultimate paragraph). Singh et al (1992, Plant Science) also teach that different types of cytokinins are present in various plant tissues of various plant species (see, e.g., page 152, paragraph bridging the columns; column 2, penultimate paragraph).

Singh et al (1992, Journal of Experimental Botany) teach that exogenous applications of cytokinins did not completely restore fertility to male sterile mutants of Brassica (see, e.g., page 1497, Abstract, last sentence of the first paragraph).

Shukla et al teach that application of the cytokinin dihydrozeatin did not restore fertility to male sterile buds (see, e.g., page 1498, paragraph bridging the columns; page 1499, column 1; page 1501, paragraph bridging the columns; pages 1502-1503). Shukla et al also teach that the closely related plant species of Arabidopsis and Brassica differ in their ability to metabolize cytokinins in male sterile tissue (see, e.g., paragraph bridging pages 1502 and 1503).

Huang et al (2003) teach that cytokinin application should occur before formation of male tissues, in order to obtain complete fertility restoration, and that continuous applications may be required (see, e.g., page 1276, column 2, top paragraph; paragraph bridging pages 1277 and 1278). Huang et al also teach that the use of thidiazuron applications failed to completely restore fertility (see, e.g., page 1273, paragraph bridging the columns and Table 1).

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Given the claim breadth, unpredictability, and lack of guidance as discussed above, undue experimentation would have been required by one skilled in the art to isolate a multitude of *gai* genes from a multitude of unrelated plant species, and to evaluate the ability of a multitude of exemplified or non-exemplified *gai* genes to confer reversible male sterility on plants transformed therewith. Undue experimentation would have also been required to evaluate a multitude of non-exemplified promoters for their ability to effect complete male sterility, or to evaluate a variety of non-exemplified cytokinins and application times for their ability to reverse said male sterility.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-2 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 97/29123 (JOHN INNES CENTRE), submitted by Applicant.

The claims are drawn to a method for transforming a plant with a *gai* coding sequence under the control of a constitutive promoter.

JOHN INNES CENTRE teaches tobacco and Arabidopsis plant transformation with the *gai* coding sequence under the control of its own promoter or the constitutive CaMV 35S promoter (see, e.g., page 44, line 17 through page 45, line 20). Since the method steps and starting materials as

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claimed are the same as those taught by the reference, the resultant transformed plants would have been inherently male sterile.

Claims 1-2 are rejected under 35 U.S.C. 102(b) as being anticipated by Peng et al (1999).

Peng et al teach rice plant transformation with the *gai* coding sequence operably linked to the constitutive ubiquitin promoter, wherein said rice plants are advantageously dwarfed (see, e.g., pages 260-261). Since the method steps and starting materials as claimed are the same as those taught by the reference, the resultant transformed plants would have been inherently male sterile.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 35 is rejected under 35 U.S.C. 103(a) as being unpatentable over WO 97/29123 (JOHN INNES CENTRE) in view of Tomes et al (US 6,258,999 filed May 1995).

The claim is drawn to a corn plant transformed with a *gai* gene.

JOHN INNES CENTRE teaches the advantages of crop plant transformation with a dwarfing gene such as the *gai* gene, teaches tobacco and Arabidopsis transformation therewith, and suggests maize transformation therewith (see, e.g., pages 1-3; 44-45).

JOHN INNES CENTRE does not explicitly teach transformed maize plants comprising the *gai* gene.

Tomes et al teach a method for maize transformation, and suggest its use for the introduction of a variety of genes conferring a variety of agronomic traits (see, e.g., column 1, lines 35-45; columns 6-12).

It would have been obvious to one of ordinary skill in the art to utilize the method of plant transformation with the dwarf-inducing *gai* gene as taught by JOHN INNES CENTRE, and to modify that method by incorporating the method of corn transformation taught by Tomes et al, as suggested by each reference.

Claim 35 is rejected under 35 U.S.C. 103(a) as being unpatentable over Peng et al (1999) in view of Tomes et al (US 6,258,999 filed May 1995).

Peng et al teach a microprojectile-mediated method of rice transformation with the *gai* coding sequence under the control of the maize ubiquitin promoter for the obtention of dwarf rice plants, and suggest the transformation of any transformable crop species for the advantageous reduction in plant height and increase in yield (see, e.g., pages 260-261).

Peng et al do not teach corn transformation.

Tomes et al teach a microprojectile-mediated method for maize transformation, and suggest its use for the introduction of a variety of genes conferring a variety of agronomic traits, as discussed above.

It would have been obvious to one of ordinary skill in the art to utilize the method of cereal plant transformation with the dwarf-inducing *gai* gene as taught

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by Peng et al, and to modify that method by incorporating the method of corn transformation taught by Tomes et al, as suggested by each reference.

Claims 1-4, 20-25 and 27-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over each of WO 97/29123 (JOHN INNES CENTRE) and Peng et al (1999), in view of Van Dun et al (US 6,603,064 filed July 2000), further in view of Koornneef et al (1980, Abstract relied upon).

The claims are broadly drawn to plant transformation with the *gai* coding sequence under the control of a male tissue-specific promoter, for the obtention of male-sterile plants, and the resultant plants and progeny thereof.

Each of JOHN INNES CENTRE and Peng et al (1999) teach plant transformation with the *gai* coding sequence, and suggest the broad applicability of the transformants, as discussed above.

Neither JOHN INNES CENTRE nor Peng et al (1999) explicitly teach that plants transformed with the *gai* gene will be male-sterile, or that a male tissue-specific promoter should be employed.

Van Dun et al teach the advantages of obtaining male sterile plants, and teach the use of a male tissue-specific promoter operably linked to the coding sequence which confers male sterility, as well as the obtention of selfed or hybrid progeny therefrom (see, e.g., column 3, lines 23-43; column 4, lines 18-28; column 5, lines 7-25 and 46-63; column 7, lines 12-46; column 12, lines 23-67; column 13, line 58 through column 16, line 39).

Koornneef et al teach that the *gai* mutation confers sterility to plants containing it (see Abstract).

It would have been obvious to one of ordinary skill in the art to obtain plants transformed with the *gai* coding sequence as taught by each of JOHN INNES CENTRE and Peng et al, and to modify those plants by incorporating a male tissue-specific promoter taught by Van Dun et al, for the obtention of male sterile plants as suggested by Koornneef et al.

Claims 1-11, 20-25 and 27-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over each of WO 97/29123 (JOHN INNES CENTRE) and Peng et al (1999), in view of Van Dun et al (US 6,603,064 filed July 2000), further in view of Koornneef et al (1980, Abstract relied upon), further in view of Ahokas.

The claims are broadly drawn to plant transformation with the *gai* coding sequence under the control of a male tissue-specific promoter, for the obtention of reversibly male-sterile plants, and the resultant plants and progeny thereof, wherein applications of cytokinin effect restoration of male fertility.

Each of JOHN INNES CENTRE and Peng et al (1999) teach plant transformation with the *gai* coding sequence, and suggest the broad applicability of the transformants, as discussed above.

Neither JOHN INNES CENTRE nor Peng et al (1999) explicitly teach that plants transformed with the *gai* gene will be male-sterile, that a male tissue-specific promoter should be employed, or that cytokinin applications may be used to restore fertility.

Van Dun et al teach the advantages of obtaining male sterile plants, and teach the use of a male tissue-specific promoter operably linked to the coding sequence which confers male sterility, as well as the obtention of selfed or hybrid

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progeny therefrom, as stated above. Van Dun et al also teach the advantages of reversible male sterility for the restoration of male fertility, for the propagation of the male sterile genotype, and also teach the ease of plant hormone application for fertility restoration (see, e.g., column 2, lines 13-17; column 9, lines 1-8; column 17, line 30 through column 18, line 16; column 16, lines 38-51).

Koornneef et al teach that the *gai* mutation confers sterility to plants containing it (see Abstract).

Ahokas teach the involvement of cytokinins in male fertility restoration (see, e.g., page 7605).

It would have been obvious to one of ordinary skill in the art to obtain plants transformed with the *gai* coding sequence as taught by each of JOHN INNES CENTRE and Peng et al, and to modify those plants by incorporating a male tissue-specific promoter taught by Van Dun et al, for the obtention of male sterile plants as suggested by Koornneef et al. Furthermore, it would have been obvious to utilize cytokinin applications for fertility restoration, as suggested by Van Dun et al and Ahokas. Adjustment of surfactant concentration would have been the optimization of process parameters.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David T. Fox whose telephone number is 571-272-0795. The examiner can normally be reached on Monday through Friday from 10:30AM to 7:00PM.

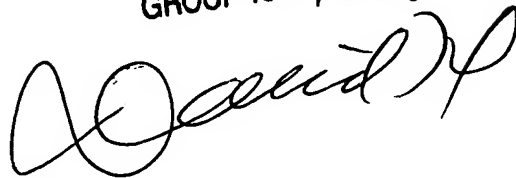
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on 571-272-0745. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system: Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

September 18, 2005

DAVID T. FOX
PRIMARY EXAMINER
GROUP ~~180~~ 1638

A handwritten signature in black ink, appearing to read "David T. Fox", written over the printed name and title.